UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,661	02/19/2004	Syed Rizvi	976	2178

67911 7590 03/03/2009

HPIF
P.O. BOX 4442
CHESTERFIELD, MO 63006-4442

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
03/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,661	RIZVI, SYED	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment and request of RCE, both filed 12/23/2008.

Claims 1-10 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/23/2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 5 have closed language with regard to

the liquid composition: "consisting of", however, the amounts of the ingredients when added up constitute from 4.78 to 7.1% by volume of the liquid composition, therefore permitting the presence of other ingredients in the liquid composition to the 100%. For purpose of prosecution, the claims are interpreted as open-ended "comprising" claim.

4. Claims 2 and 6 recite the limitation "solvent" in the 1st line of each claim. There is insufficient antecedent basis for this limitation in the claim.

5. Claims 4 and 7 recite the closed language: "composition consists of an aqueous solution" and this is followed by the open ended recitation of "the aqueous solution containing". It is not clear to examiner as applicant's intention regarding the claim language.

6. Claims 4 and 7 depends on claims 1 and 5 respectively, and claims 1 and 5 closed the components of the liquid composition by the language "consisting of" while claims 4 and 7 reopen the components of the liquid composition to other components. It is not clear to examiner as applicant's intention regarding the claim language. A claim which depends from a claim which recites elements or steps as "consists of", cannot add an element or step.

For purpose of prosecution, the claims are interpreted as open-ended "comprising" claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-3, 5, 6, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article "Compendium of Pharmaceutical Excipients for Vaginal Formulations" by Garg et al. by itself or combined with US 2002/0142690 ('690).

Garg et al. teach ideal vaginal formulation with desired characteristics in terms of safety, efficacy, patient compliance, aesthetic, acceptability to regulatory authorities, and cost requirements (page 14). Garg et al. teach towel to clean external vaginal area comprising lactic cid, water, potassium sorbate, O-9 (octoxynol-9), EDTA, cetylpyridinium chloride, and fragrance (page 17). Garg et al. further teach absorbent cotton in tampons as a carrier (top of page 18), and absorbent cotton tampon implies that it absorbs the composition applied to it to form impregnated substrate. Garg et al. teach amount of lactic acid is between 0.015 -6.6 %; amount of potassium sorbate is between 0.1-0.2%; amount of emulsifier can be as low as 0.3% for polyoxyethylene-polyoxypropylene copolymer, 0.5% for sodium lauryl sulfate, or 0.3-0.55 for cholesterol; amount of EDTA is between 0.01-0.1%; amount of preservative is between 0.01-0.02%

(pages 18-22). Garg et al. teach alum potassium in the composition (page 18), claimed by applicant as odor absorbing agent.

Although Garg et al. teach all the ingredients of the product as instantly claimed, however, the reference does not explicitly teach the amount of the odor absorbing agent, or amount of antiseptic cetylpyridinium.

Garg et al. suggest the generic teaching of the amount of preservatives as low as 0.1-0.2% for benzoic acid that is known as antiseptic agent.

Although Garg et al. do not specifically teach the amounts of some ingredients as claimed by applicant, however, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide towel or tampon impregnated with the composition disclosed by Garg et al., and optimize the amounts of different ingredients in order to achieve the desired anti-infective effect and mean while maintaining pleasant odor of the composition.

Although Garg et al. implies the composition is absorbed into a substrate, however, Garg et al. does not explicitly teach the impregnation of the composition in the absorbent article.

US '690 teaches substrate of web fabric impregnated with composition comprising octooxynol-9, and deliver impregnated material upon wiping the contaminated surface, and avoid re-positioning the contaminant upon the surface which is being cleaned (abstract; paragraphs: 0023, 0025, 0029, 0031). The wipes can be handled safely, non-toxic, and even if misplaced poses little or no risk to the end user, and far more effective at removing stubborn embarrassing contaminants helping preventing sexually transmitted diseases (paragraph 0034).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide towel or tampon comprising the composition disclosed by Garg et al., and optimize the amounts of different ingredients to obtain specific desired effect such as anti-infective effect, and further apply the composition to the towel or tampon by impregnation as disclosed by US '690. One would have been motivated to do so because Us '690 teaches that wipes impregnated with anti-infective composition can be handled safely, and even if misplaced poses little or no risk to the end user, and far more effective at removing stubborn embarrassing contaminants helping preventing sexually transmitted diseases. One would have reasonably expected treating vaginal contamination safely and effectively with reduction of the risk of transmitting sexually transmitted diseases using substrate impregnated with the composition disclosed by Garg et al.

Response to Arguments

9. Applicant's arguments filed 12/23/2008 have been fully considered but they are not persuasive.

Applicant argues that the present claims as amended use the language "consists of" that excludes the presence of any element, step or ingredient not specified by the claim. Garg et al. require fragrance.

In response to this argument, it is argued that although claims 1 and 5 recite utilize the language "consist of", however, the ingredients recited by the claims do not form 1005 of the composition, therefore permitting the presence of other ingredients such as fragrance disclosed by Garg et al. It has been held that omission of an element and its function is obvious if the function of the element is not desired. *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

Applicant argues that each different formulation disclosed in Garg et al. is correlated with its own indication or therapeutic use. The Examiner cites a composition from Garg et al. that does not disclosed for treating vaginitis

In response to this argument, applicant's attention is directed to the scope of the present claims: claim 1 is product and claim 5 is method of treating vaginitis comprising one step of applying the claimed composition. All the elements of the product are disclosed by the Grag et al. by itself or combined with US '690. The claimed method

requires one step of applying the composition to the affected body area, and Grag et al. disclosed that step. Grag et al. in page 15, at the bottom of the left column, stated that "Vaginal administration of drugs is mainly used for the treatment of local infections such as vaginitis, bacterial vaginosis, candidiasis and other infection". Further, Grag et al. in page 15, at the top of the right column, stated that: "Vaginally administered agents and formulations are mainly used and are being developed to provide protection against microbial infections." Therefore, treatment of vaginitis is the main goal of Grag's reference, and further disclosed many formulations to achieve such a goal. The composition used as cleansing for the skin is expected to have anti-infective effect to treat vaginitis because Grag et al. in page 15, right column, teaches that the ingredients normally used as excipients possess potent antimicrobial activities, and further listed surfactants as example. Therefore, the ingredients used to cleanse the skin as disclosed by Grag et al. are expected to provide antimicrobial activities. Additionally, cleansing the skin with wipe or towelette will remove materials attached to the surface of the skin including dirt, secretion and microbes that cause vaginitis. The ingredients disclosed by the reference as cleanser are expected to have anti-infective effect when applied to the vagina since materials and their properties are inseparable.

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

10. Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garg et al., or over the combination of Garg et al. and US '690, and further in view of the article "Natural Deodorant" by Carrubba Inc.

The article "Natural Deodorant" by Carrubba Inc. was available before 11/13/2001, the date it was faxed to applicant. This implies that the article was available before that date 11/13/2001.

The teaching of Garg et al. by itself or combined with US '690 are discussed above. The teachings suggest all the ingredients in almost the claimed amounts.

However, Garg et al. by itself or combined with US '690 do not teach saccharomyces ferment as claimed by claims 4 and 7.

The article by Carrubba Inc. teaches saccharomyces ferment used as personal deodorant for feminine hygiene. The product is safe to be used on and around human and it is non-toxic, non-irritating, and non-allergenic (first page).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide towel or tampon impregnated with composition comprising the ingredients disclosed by Garg et al. by itself or combined with US '690, and replace the fragrance element from the composition with saccharomyces ferment disclosed by Carrubba Inc. One would have been motivated to do so because the

Carrubba article teaches that saccharomyces ferment is safe to be used on and around human and it is non-toxic, non-irritating, and non-allergenic. One would have reasonably expected formulating substrate to be used on the genitalia impregnated with composition disclosed by Garg et al., and further comprising saccharomyces ferment that is deodorant for feminine hygiene articles and further is non-toxic, non-irritating, and non-allergenic that effectively, safely and pleasantly disinfect the site of wiping.

Response to Arguments

11. Applicant's arguments filed 12/23/2008 have been fully considered but they are not persuasive.

Applicant argues that claims 4 and 7 as amended exclude the use of fragrance in the liquid composition. The combination of the references does not teach all the elements of claim 4 and 7 and the claims are not obvious over the references because the specific quantity of odor controlling agent is not disclosed.

In response to this argument, applicant' attention is directed to the scope of claims 4 and 7 that does not exclude the presence of other ingredients because the claims utilize the language "containing" with regard to the composition. Additionally, elimination of an element and its function is obvious if the element is not desired. *Ex parte Wu* , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975). Odor controlling agent and fragrance are both added to personal care

products to eliminate undesired odors, and it is personal choice to select either or both in the product according to intended use.

It is further argued that all the elements of the product claims are taught by the combined teachings of the prior art and the only step of the method claims is taught by the prior art. The article by Carrubba Inc. is relied upon for teaching the specific odor controlling agents claimed by claims 4 and 7. Carrubba Inc. teaches saccharomyces ferment used as personal deodorant for feminine hygiene. The product is safe to be used on and around human and it is non-toxic, non-irritating, and non-allergenic, and this teaching would have been motivated one having ordinary skill in the art to include saccharomyces ferment in feminine personal hygiene products, with reasonable expectation of having substrate to be used on the genitalia impregnated with composition disclosed by Grag et al., and further comprising saccharomyces ferment that is deodorant for feminine hygiene articles and further is non-toxic, non-irritating, and non-allergenic that effectively, safely and pleasantly disinfect the site of wiping.

Regarding the amount of a specific ingredient in a composition, it is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention. The odor control is known property of

saccharomyces ferment, and is not new and unexpected, and determination of its amount is within the ability of skilled artisan without undue experimentation in order to achieve the desired degree of odor control.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

IG